CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

FDA Approves First Trial Based on Human Embryonic Stem Cells

On January 21 the Food and Drug Administration approved the first Investigational New Drug Application for a clinical trial using cells derived from embryonic stem cells. This announcement allows San Mateo-based Geron Corporation to proceed with a clinical trial for spinal cord injury within federal safeguards.

"The California Institute for Regenerative Medicine congratulates Geron for reaching this milestone; this is a significant step forward in the field of regenerative medicine," said Alan Trounson, president of CIRM. "A great deal will be learned from this trial and that will impact the entire field of research."

The cell-based therapy that will be tested in the Phase I trial is based on work by Hans Kierstead, co-director of the Sue and Bill Gross Stem Cell Research Center, and his colleagues at UC Irvine. Kierstead now has a Comprehensive grant from CIRM.

In a statement from UC Irvine, Kierstead said, "This trial was approved only after rigorous safety testing and consultation of countless experts in the field. Any benefit to the patient, even an incremental one, would be a resounding victory."

Geron has said they have selected up to seven U.S. medical centers to conduct the trial, which will include eight to ten people who have received spinal cord injuries within the previous 14 days. This initial trial is intended to test the safety of the investigational therapy. If it proves to be safe they will move on to a larger Phase II trial that will assess whether it is effective.

"This marks the beginning of what is potentially a new chapter in medical therapeutics - one that reaches beyond pills to a new level of healing: the restoration of organ and tissue function achieved by the injection of healthy replacement cells," said Thomas Okarma, president and CEO of Geron.

Trounsan said the CIRM Disease Team Awards, which will be given out later this year, will help bring additional human embryonic stem cell-based therapies to clinical trials. These awards will go to teams of researchers working together to develop basic research into therapies that could benefit the millions of people with debilitating diseases.

 Hans Kierstead talks about hurdles in developing new therapies

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